

EXHIBIT 1**STATEMENT OF ADMITTED FACTS**

1. On May 22, 1989, Michael Boneau and ACS entered into a Mutual Confidentiality Agreement.
2. On August 21, 1989, Michael Boneau, on behalf of Accuterix, Inc., and ACS entered into a Nondisclosure Agreement.
3. On August 24, 1989, U.S. Application Ser. No. 07/398,180 to Michael D. Boneau, entitled "Endovascular Support Device," was filed with the PTO ("Boneau Patent Application").
4. The Boneau Patent Application issued as United States Patent No. 5,292,331 ("Boneau '331 Patent") on March 8, 1994.
5. On August 24, 1990, European Application No. 90309339.1 to Michael D. Boneau, entitled "Endovascular Support Device and Method," was filed with the European Patent Office ("Boneau European Application"). The Boneau European Application was published on March 20, 1991.
6. On October 28, 1991, U.S. Application Ser. No. 07/783,558 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is now abandoned.
7. On December 9, 1993, U.S. Application Ser. No. 08/164,986 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a continuation of U.S. Application Ser. No. 07/783,558, which is now abandoned.
8. On March 17, 1994, U.S. Application Ser. No. 08/214,402 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making

Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/164,986, which is now abandoned.

9. U.S. Application Ser. No. 08/214,402 issued as U.S. Patent No. 5,421,955 on June 6, 1995.

10. On July 28, 1994, U.S. Application Ser. No. 08/281,790 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents," was filed with the PTO. This application is a continuation-in-part of U.S. Application Ser. No. 08/164,986, which is now abandoned.

11. U.S. Application Ser. No. 08/281,790 issued as U.S. Patent No. 5,514,154 on May 7, 1996.

12. On November 13, 1995, U.S. Application Ser. No. 08/556,516 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/281,790, which issued as U.S. Patent No. 5,514,154.

13. U.S. Application Ser. No. 08/556,516 issued as U.S. Patent No. 5,603,721 on February 18, 1997.

14. On January 14, 1997, U.S. Application Ser. No. 08/783,033 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/556,516, which issued as U.S. Patent No. 5,603,721.

15. On August 28, 1997, during prosecution of the '033 application, ACS submitted an information disclosure statement (IDS). That IDS identified two references, one of which was the Boneau '331 Patent.

16. U.S. Application Ser. No. 08/783,033 issued as U.S. Patent No. 5,728,158 on March 17, 1998.

17. On January 14, 1997, U.S. Application Ser. No. 08/783,097 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/556,516, which issued as U.S. Patent No. 5,603,721.

18. On August 27, 1997, during prosecution of the '097 application, ACS submitted an information disclosure statement (IDS). That IDS identified two references, one of which was the Boneau '331 Patent.

19. U.S. Application Ser. No. 08/783,097 issued as U.S. Patent No. 5,735,893 on April 7, 1998.

20. On March 24, 1997, U.S. Application Ser. No. 08/823,434 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/783,097, which issued as U.S. Patent No. 5,735,893. U.S. Application Ser. No. 08/823,434 issued as U.S. Patent No. 5,766,238 on June 16, 1998.

21. On May 26, 1998, U.S. Application Ser. No. 09/084,797 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/823,434, which issued as U.S. Patent No. 5,766,238. U.S. Application Ser. No. 09/084,797 issued as U.S. Patent No. 6,066,167 on May 23, 2000.

22. On April 6, 1998, U.S. Application Ser. No. 09/055,582 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making

Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 08/783,097, which issued as U.S. Patent No. 5,735,893. U.S. Application Ser. No. 09/055,582 issued as U.S. Patent No. 6,066,168 on May 23, 2000.

23. On August 17, 1998, U.S. Application Ser. No. 09/135,222 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 09/055,582, which issued as U.S. Patent No. 6,066,168. U.S. Application Ser. No. 09/135,222 issued as U.S. Patent No. 6,056,776 on May 2, 2000.

24. On April 28, 2000, U.S. Application Ser. No. 09/561,098 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 09/135,222 which issued as U.S. Patent No. 6,056,776. U.S. Application Ser. No. 09/561,098 issued as U.S. Patent No. 6,309,412 on October 30, 2001.

25. On November 16, 2000, U.S. Application Ser. No. 09/716,847 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 09/561,098, which issued as U.S. Patent No. 6,309,412. U.S. Application Ser. No. 09/716,847 issued as U.S. Patent No. 6,432,133 on August 13, 2002.

26. On November 16, 2000, U.S. Application Ser. No. 09/715,415 to Lilip Lau, William M. Hartigan, and John J. Frantzen, entitled "Expandable Stents and Method for Making Same," was filed with the PTO. This application is a division of U.S. Application Ser. No. 09/561,098, which issued as U.S. Pat. No. 6,309,412. U.S. Application Ser. No. 09/715,415 issued as U.S. Patent No. 6,511,504 on January 28, 2003.

EXHIBIT 2

MEDTRONIC'S STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

1. Whether ACS, its counsel, and/or those substantively involved in the preparation, filing, and prosecution of any of the applications that issued as the Lau Patents committed inequitable conduct by making affirmative misrepresentations of material fact, failing to disclose material information, and/or submitting false material information to the PTO with an intent to deceive.
2. Whether any of the Lau Patents are unenforceable due to inequitable conduct.
3. Whether any of the Lau Patents are unenforceable due to infectious inequitable conduct.
4. Whether this is an exceptional case under 35 U.S.C. §285.

EXHIBIT 3**STATEMENT OF ISSUES OF FACT
REMAINING TO BE LITIGATED**

1. Whether Medtronic has proved by clear and convincing evidence that ACS committed inequitable conduct.
2. Whether the Boneau patent application was cumulative to art cited to the patent office during prosecution of the Lau patent applications.
3. Whether the Boneau patent application was material to patentability.
4. If the Boneau patent application was material to patentability, whether the inventors or patent attorneys responsible for prosecuting the Lau patent applications actually and contemporaneously knew the Boneau application was material to patentability.
5. Whether the inventors of the Lau patents or the patent attorneys responsible for prosecuting the Lau applications had actual and specific intent to deceive the patent and trademark office.
6. Whether any allegations of inequitable conduct for failure to disclose the Boneau patent application can render unenforceable those Lau patents-in-suit in which the Boneau patent was cited during prosecution.
7. To the extent the Court allows Medtronic to pursue inequitable conduct allegations other than the failure to cite the Boneau patent application, notwithstanding that those other allegations were not properly plead and/or were abandoned by Medtronic in its interrogatory responses, other issues of fact may be raised at trial. Those issues include, e.g., (a) whether the Boneau patent and other Boneau "art" was material to patentability, (b) whether the inventors or their patent attorneys had actual and specific knowledge of such materiality and actual and specific intent to deceive the

patent and trademark office, (c) whether Medtronic's allegations concerning the Palmaz patent are factually correct, (d) whether Medtronic's allegations concerning the alleged contribution to the Lau patents by Mr. Boneau are factually correct, (e) whether Medtronic's allegations concerning alleged "examiner shopping" are correct, (f) whether Medtronic has proved by clear and convincing evidence any of these additional allegations of inequitable conduct, and (g) whether any of these additional allegations have the requisite "immediate and necessary relationship" required to "infect" other patents in the Lau patent family.

EXHIBIT 4**MEDTRONIC'S STATEMENT OF ISSUES OF LAW****I. INEQUITABLE CONDUCT**

Applications for patents are prosecuted by applicants and examined by the United States Patent and Trademark Office (“PTO”) on an *ex parte* basis, not in an adversarial forum. *Norton v. Curtiss*, 433 F.2d 779, 793-94 (C.C.P.A. 1970). Moreover, the PTO has only a limited amount of time and resources to review every one of the multitude of applications that are filed every year for patentability. *Id.* at 794. As a result, the PTO is in a position in which it must rely on applicants and their agents to provide “many of the facts upon which its decisions are based.” *Id.* Thus, the law imposes on all applicants and their agents an affirmative duty to deal with the PTO with “candor, good faith, and honesty” and also to disclose to the PTO all information that is known and material to the examination of the application. *Precision Instrument Mfg. Co. v. Automotive Main. Mach. Co.*, 324 U.S. 806, 818 (1945) (“Public interest demands that all facts relevant to such matters be submitted . . . to the [PTO], which can then pass upon the sufficiency of the evidence.”); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

The duty of candor and disclosure is an “uncompromising” duty that must be fulfilled with “the highest degree of candor and good faith.” *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949) (“In its relation to applicants, the [PTO] must rely upon their integrity, and [thus the PTO deals] with them in a spirit of trust and confidence.”); *Precision*, 324 U.S. at 818 (“Only in this way can [the PTO] act to safeguard the public in the first instance against fraudulent patent monopolies.”); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538 (Fed. Cir. 1984) (“[t]he highest standards of honesty and candor on the part of applicants in presenting such facts to the [PTO] are thus necessary elements in a working patent system. We would go so far as to say they are essential.””).

The duty of candor and disclosure extends to all persons who are substantively involved in the preparation, filing, and prosecution of patent applications, including inventors, attorneys, and their representatives. *Molins*, 48 F.3d at 1178, n6. Although the duty generally does not extend broadly to corporations, it does apply to individuals within the corporation who are substantively involved in the patenting process, and it also applies to corporate records and other forms of corporate information that are known or reasonably should have been known by those who are substantively involved in the patenting process. Manual of Patent Examining Procedure §2001 (1989) (“MPEP (1989)”).¹

Absent notice of the existence of material information, applicants and their agents generally do not have a duty to investigate or to conduct a prior art search. *Brasseler, U.S.A. I v. Stryker Sales Corp.*, 267 F.3d 1370, 1382 (Fed. Cir. 2001). However, if applicants or their agents are placed on notice of the existence of information that may be material, the duty of candor and disclosure includes a duty of inquiry and will extend to information that the applicants and their agents knew or should have known was material. *Id.* at 1382-84; MPEP §2001.02 (1989) (“[I]f an applicant or an applicant’s attorney is aware of facts which indicate a reasonable possibility that a bar to patenting or information material to [the] examination may exist, they are expected to make reasonable inquiries to ascertain such information and to submit such to the [PTO].”). Applicants and their agents cannot “cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art.” *Brasseler*, 267 F.3d at 1383 (citation omitted); *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989) (applicants and their agents cannot engage in a “[s]tudied ignorance” of the facts and a “reckless indifference” to the truth).

¹ Although “the MPEP does not have the force of law, it is entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith.” *Molins*, 48 F.3d at 1180 n10.

The duty of candor and disclosure is irrespective of the source of the information or how the information became known to applicants and their agents. MPEP §2001.06 (1989) (“Materiality controls whether information must be disclosed . . . not the circumstances under which or the source from which the information is obtained. If material, the information must be disclosed . . .”). “Once an attorney, or an applicant, has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose.” *Brasseler*, 267 F.3d at 1383 (citation omitted).

The duty of candor and disclosure is a continuing one that exists from the time an application is filed with the PTO until the time the patent issues. *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990); MPEP §2001.06 (1989) (“The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof.”).

A breach or violation of the duty of candor and disclosure by an “affirmative misrepresentation of material fact, failure to disclose material information, or submission of false material information to the PTO, coupled with an intent to deceive,” constitutes inequitable conduct, and acts as a defense to a claim of patent infringement. *Li Second Family Ltd. v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000); *Molins*, 48 F.3d at 1178.

II. BURDENS OF PROOF

A party asserting inequitable conduct bears the burden of proving by clear and convincing evidence that (1) the applicant or the applicant’s agents made a misrepresentation or nondisclosure that was material and (2) the applicant or the applicant’s agent acted with an intent to deceive. *Li*, 231 F.3d at 1378. Upon a threshold showing of materiality and intent, the court must weigh the evidentiary showing on both elements to determine whether the equities warrant a finding of inequitable conduct. *Id.* The more material the misrepresentation or omission, the

less evidence of intent is required. *Id.* at 1378-79; *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (“Questions of ‘materiality’ and ‘culpability’ are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established, whereas a greater showing of the materiality of withheld information would necessarily create an inference that its nondisclosure was ‘wrongful.’” (citation omitted)).

A prima facie showing of inequitable conduct can be made by establishing “an unexplained violation of the duty of candor.” *Paragon Podiatry Lab. v. KLM Lab., Inc.*, 984 F.2d 1182, 1192 (Fed. Cir. 1993). Upon a prima facie showing, the burden of proof shifts to the patent holder to come forward with evidence which negates a finding of inequitable conduct. *Id.* at 1191. A patent holder’s mere averments that he acted with good faith or lacked a deceptive intent is insufficient to carry the burden of negating a finding of inequitable conduct. *Id.* at 1190; *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994). Similarly, a patent holder’s “conclusory statements or completely unsupportable, specious, or conflicting explanations or excuses [also] will not suffice . . .” to meet this burden. *Paragon*, 984 F.2d at 1190.

III. MATERIALITY

“Information is ‘material’ when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.” *Molins*, 48 F.3d at 1179. All doubts regarding materiality should be resolved in favor of disclosure to the PTO. MPEP §2004(10) (1989) (“When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn’t consider it necessarily material, someone else may see it differently and embarrassing

questions can be avoided.”); Manual of Patent Examining Procedure §2001.04 (1992) (“MPEP (1992)”) (“It is the patent examiner who should make the determination after considering all of the facts involved in the particular case.”); *id.* (“The Office encourages applicants to carefully examine: . . . the closest information over which individuals associated with the filing and prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.”); *LaBounty Mfg., Inc. v. ITC*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (“Close cases should be resolved by disclosure, not unilaterally by the applicant.”).

“In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents.” *Fox*, 922 F.2d at 803. “Therefore, a breach of the duty of candor [and disclosure] early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.” *Id.* at 804. Thus, a breach of the duty of candor and disclosure generally cannot be “cured” by amendments to the claims. *Perceptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 (Fed. Cir. 2000); *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1396-97 (Fed. Cir. 1986).

A. Misrepresentation of Fact

A misrepresentation of fact may be deemed material if a reasonable examiner would consider the misrepresentation important in deciding whether to issue the patent. *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989) (misrepresentation of fact may be deemed material if it is “within a reasonable examiner’s realm of consideration.”); *Li*, 231 F.3d at 1379-80 (misrepresentation regarding the application priority date was material); *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1364-65 (Fed. Cir. 2003) (failure to identify a co-pending application covering the similar subject matter was material). However,

a misrepresentation of fact also may be deemed material even if it is independent of the claimed invention. *Perseptive*, 225 F.3d at 1322 (providing false information relating to inventorship was material); *General Electro*, 19 F.3d at 1411 (a false statement that the patentee had conducted a prior art search was material); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (“there is no room to argue that submission of false affidavits is not material.”).

A misrepresentation or incorrect characterization of a prior art reference may be deemed material even where the patent examiner had access to the references. *Akzo N.V. v. ITC*, 808 F.2d 1471, 1482 (Fed. Cir. 1986). Indeed, there is no “per se” rule that inequitable conduct cannot be found where misrepresented prior art is before the PTO. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys.*, 63 F. Supp. 2d 1064, 1076 (N.D. Cal. 1999) (listing cases). Instead, “a lapse on the part of an examiner does not exculpate an applicant whose acts are intentionally deceptive . . . [n]or does the applicant’s obligation of candor replace the examiner’s duty to examine the claims.” *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 938 (Fed. Cir. 1990); *KangaRoos USA, Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985) (“There is no reprieve from the duty of square dealing and full disclosure that rests on the patent practitioner in dealings with the PTO.”); *Semiconductor Energy Lab. Co. v. Samsung Electronics Co.*, 4 F. Supp. 2d 477, 494-95 (E.D. Va. 1998), aff’d, 204 F.3d 1368 (Fed. Cir. 2000) (finding inequitable conduct where the applicant made misrepresentations relating to a Japanese prior art reference and the examiner did not have a full translation of the reference that would have highlighted the misrepresentations). In *Semiconductor Energy*, the district court stated:

It is worth noting that advocacy before the PTO is appropriate. But, there is a line between legitimate advocacy in accordance with the duty of candor, and advocacy that the applicant surely knows has a propensity to mislead the examiner. Here, that line was crossed.

Id. at 495, n36.

B. Failure to Disclose Prior Art

An undisclosed prior art reference may be deemed material if a reasonable examiner would consider the reference important in deciding whether to issue the patent. *A.B. Dick*, 798 F.2d at 1397. The threshold inquiry of materiality of an undisclosed prior art reference requires a factual analysis of the relevance of the teachings of the reference along with the claims at issue and the prior art that was before the examiner. *Dayco*, 329 F.3d at 1367.

An undisclosed prior art reference may be deemed material even if it would not have led to a rejection of any claims asserted in the application. *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1213 (Fed. Cir. 1987) (“The simple fact is that a patent may be valid and yet be rendered unenforceable for misuse or inequitable conduct.”); *A.B. Dick*, 798 F.2d at 1397 (“[T]he test for materiality is not whether there is anticipation or obviousness but, rather, what a reasonable examiner would consider . . . important in deciding whether to allow the application to issue as a patent.”).

The Federal Circuit has found an undisclosed prior art reference to be material or even “highly material” when it discloses a number of relevant features or suggests a combination of some of the elements of the claimed invention. *Semiconductor*, 204 F.3d at 1374; *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1328 (Fed. Cir. 1998). The Federal Circuit has also found an undisclosed prior art reference material or even “highly material” when it “discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references.” *Semiconductor*, 204 F.3d at 1374.

IV. INTENT

“Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor.” *Molins*, 48 F.3d at 1189. In other words, a “smoking gun” is not required to prove intent. *Merck*, 873 F.2d at 1422. Indeed, direct proof of intent, or a “smoking gun,” is rarely available, and thus intent may and can be inferred from evidence of the surrounding circumstances. *Baxter*, 149 F.3d at 1329; *LaBounty*, 958 F.2d at 1076. An inference of intent is warranted where any applicant or its agent knew or should have known that the misrepresented or withheld information would be material to the PTO’s examination. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 759 F.2d 10, 14-15 (Fed. Cir. 1985). For that reason, the party asserting inequitable conduct does not have to show the subjective state of mind of the applicant or the applicant’s agent in proving intent. *Rohm*, 722 F.2d at 1571.

The Federal Circuit has found sufficient evidence of an intent to deceive in a number of scenarios.

First, the Federal Circuit has held that proof that an applicant or an applicant’s agents failed to disclose a material prior art reference, combined with proof that the applicant knew or should have known of the materiality, “makes it difficult to . . . overcome an inference of intent to mislead.” *Semiconductor*, 204 F.3d at 1375; *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n7 (Fed. Cir. 1987) (“overwhelming showing of materiality plus an applicant’s knowledge of that materiality may raise an inference of intent so strong as to require a convincing showing of subjective good faith to offset it.”); *D.O.C.C., Inc. v. Spintech, Inc.*, 36

U.S.P.Q.2d (BNA) 1145, 1153 (S.D.N.Y. 1994) (intent to deceive can be inferred from an applicant's inexplicable failure to disclose a known and material prior art reference).

Second, the Federal Circuit has found that proof that an applicant or an applicant's agent engaged in a "studied ignorance" of the facts was sufficient to create an inference of intent. *Brasseler*, 267 F.3d at 1380-85.

Third, the Federal Circuit has found intent where neither the inventor nor the prosecuting attorney testified at trial, despite a contractual commitment to do so. *A.B. Dick*, 798 F.2d at 1399-1400. "When a party knows of witnesses on a material issue and they are within his control to produce, if the party chooses to not call the witnesses, the fact finder may draw the inference that the testimony would have been unfavorable." *Id.* at 1400, n9 (citation omitted).

Fourth, the Federal Circuit has found intent where there is evidence of a pattern of breaches of the duty of candor and disclosure. *Paragon*, 984 F.2d at 1191-93.

Finally, the Federal Circuit has held that the submission of a false or misleading statement to the PTO warrants an inference of intent. *General Electro*, 19 F.3d at 1411; *Paragon*, 984 F.2d at 1191. The affirmative act of submitting a false or misleading statement or concealing material facts is "particularly egregious" when it pertains to matters outside of prior art patents to which the patent examiner has no way of independently verifying. *Paragon*, 984 F.2d at 1193; *Rohm*, 722 F.2d at 1570-71 (finding that false affidavit submitted to overcome a rejection created an inference of intent to deceive).

V. SCOPE OF UNENFORCEABILITY

A finding of inequitable conduct as to just one claim renders the entire patent unenforceable. *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Moreover, the court may look beyond the final claims to their antecedent claims in

determining inequitable conduct. *Fox*, 922 F.2d at 803. A finding of inequitable conduct early in the prosecution of an application “may render unenforceable all claims which eventually issue from the same or a related patent.” *Id.* at 803-04.

VI. INFECTIOUS INEQUITABLE CONDUCT

If a patent is held to be unenforceable for inequitable conduct, decedent patents, such as continuations, continuations-in-part, and divisions, may also be rendered unenforceable.

See Consolidated Aluminum Corp. v. Fosesco Int'l, Ltd., 910 F.2d 804, 812 (Fed. Cir. 1990); *Semiconductor*, 4 F. Supp. 2d at 493; *East Chicago Mach. Tool Corp. v. Stone Container Corp.*, 181 U.S.P.Q. (BNA) 744, 748 (N.D. Ill. 1974). This theory of unenforceability, known as “infectious inequitable conduct,” is premised on the principle that the duty of candor extends through the patent’s entire prosecution history, and that a breach of the duty of candor may render unenforceable all claims which eventually issue from the same or even a related application. *Fox*, 922 F.2d at 803-804.

To prove infectious inequitable conduct, a party must establish inequitable conduct sufficient to hold at least one patent unenforceable. *Speedplay, Inc. v. Bebop*, 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an immediate and necessary relationship between the alleged inequitable conduct and enforcement of the related patents. *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 537 (D.N.J. 2000). An immediate and necessary relation between the alleged inequitable conduct and the enforcement of related patents can be shown where: 1) the related patents either expressly incorporate the procedures of the invalidated patent or are issued from continuation applications stemming from such; and 2) where the patentee’s inequitable

conduct in prosecution of the invalid patent forms a basis for its successful arguments in prosecuting the other related patents. *Id.*

EXHIBIT 5**ACS'S STATEMENT OF ISSUES OF LAW****I. INEQUITABLE CONDUCT****A. Allegations of Inequitable Conduct Are Generally Disfavored by the Courts**

The federal courts have repeatedly expressed their aversion to allegations of inequitable conduct. *See, e.g., Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Infringers have plagued the court system by routinely claiming inequitable conduct as a tactic to avoid the consequence of their infringing conduct and to “deprive patentees of their earned property rights and impugn fellow professionals.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). To protect against this misuse, parties alleging inequitable conduct must face the heavy burden of proving by clear and convincing evidence that “the applicant’s conduct is so culpable that the patent should be unenforceable.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744 (Fed. Cir. 2002).

B. The Duty to Disclose Information to the Patent Office Extends Only to Persons with Substantial Involvement in the Patent Prosecution Process

Pursuant to 37 C.F.R. § 1.56, the duty of candor applies to the named inventors, the attorneys or agents that prosecute the application, and persons “substantively involved in the preparation or prosecution of the application.” 37 C.F.R. § 1.56. The duty, however, does not apply to corporate entities.

Moreover, no significant basis exists to apply the duty of candor to corporate executives whose participation in the prosecution of a patent is limited to a function of their administrative oversight. *See Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A.*, 357 F. Supp. 2d 1105, 1119-20 (S.D. Iowa 1999) (refusing to find intent to deceive by a corporate executive

responsible for patent prosecution, calling the basis of a jury's advisory finding that the duty of candor existed "tenuous" and "shallow.").

C. The Duty of Disclosure Applies Only to Information Actually and Contemporaneously Known by the Applicants

The duty of disclosure applies only where an applicant has actual and specific knowledge of information. *See Nordberg, Inc. v. Telsmith, Inc.*, 82 F.3d 394, 397 (Fed. Cir. 1996); *see also American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (rejecting the "should have known" standard, and holding that applicants do *not* have "an obligation to disclose any art of which, in the [district] court's words, he 'reasonably should be aware.'"). An allegation of inequitable conduct simply cannot stand on the basis that an applicant "should have known" of the existence of a material reference. *See Nordberg*, 82 F.3d at 397. Rather, "the applicant's *actual knowledge* of the reference's existence must be proved" by clear and convincing evidence. *Id.* (emphasis added).

Additionally, it is not enough to suggest that an applicant knew of information at one time. Rather, the party alleging inequitable conduct must prove by clear and convincing evidence that the applicant had contemporaneous or present knowledge of the allegedly withheld information. *Nordberg*, 82 F.3d at 397. The fact that information was known years ago does not mean that it was recognized that the information is material to the present application.

II. BURDEN OF PROOF

A. Inequitable Conduct Requires Satisfaction of a Strict Burden

An allegation of inequitable conduct fails absent a showing by clear and convincing evidence that the patentees made an “affirmative misrepresentation of a material fact, fail[ed] to disclose material information, and [did] so with an intent to deceive.” *Amgen, Inc. v. Hoechst Marion Rousel*, 314 F.3d 1313, 1358 (Fed. Cir. 2003). In order to satisfy this heavy burden, the party alleging inequitable conduct must prove both materiality and intent to deceive the patent office by clear and convincing evidence. *See Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001). Additionally, by weighing the materiality of the reference and the intent to deceive the patent office, the court must conclude that the applicant’s conduct is “so culpable that the patent should be held unenforceable.” *Purdue Pharma*, 237 F.3d at 1366; *see also Juicy Whip*, 292 F.3d at 744..

As a general rule, the higher the level of materiality, the lower the necessary threshold of intent to deceive, and vice versa. *See GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1273 (Fed. Cir. 2001). A high level of materiality or intent, however, does not presume the existence of the other required element. *See Allen Organ Co. v. Kimball Int’l, Inc.*, 839 F.2d 1556, 1567 (Fed. Cir. 1988). Both materiality and intent to deceive must be proven independently. *See Id.* (“materiality does not presume intent, which is a separate and essential component of inequitable conduct.”).

III. MATERIALITY

A. The Patent Office Has Adopted a New Standard of Materiality for the Inequitable Conduct Inquiry

Prior to 1992, the materiality inquiry related to any information “a reasonable examiner would have substantially likely considered important in deciding whether or not to allow an application to issue as a patent.” 37 C.F.R. § 1.56 (1990). In 1992, however, the patent office modified the threshold for a materiality determination to “address criticism concerning a perceived lack of certainty in the materiality standard.” 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992).

The new Rule 56 standard states:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b). In other words, the revised rule 56 presents a more concrete approach to materiality, deeming a reference material only where it establishes either a “prima facie case of unpatentability” or refutes, or is inconsistent with a position taken by the applicant, and is not cumulative. *Id.*

B. The New Standard For Inequitable Conduct Applies to Applications Pending During the 1992 Rule Change

The Federal Circuit has held that, “According to the PTO’s notice of final rulemaking, the rule change applied to all applications pending or filed after March 16, 1992.” *Bruno Independent Living Aids, Inc., v. Acorn Mobility Services Ltd.*, 394 F.3d 1348 (Fed. Cir. 2005). The District of Delaware has likewise recognized that, “The governing standard for materiality is the one in place when the pertinent events of the patent prosecution occurred.” *Rhenalu v. Alcoa, Inc.*, 224 F.Supp. 2d 773, 805 (D. Del. 2002) (citing *CFMT, Inc. v. YieldUP Int’l Corp.*, 144 F.Supp. 2d 305, 316 (D. Del. 2001)).

C. Prior Art That Is Cumulative of Art Cited to the Patent Office Is Not Material to Patentability

As stated above, the revised standard of materiality establishes that information is material to patentability only when it is “not cumulative to information already of record or being made of record in the application.” 37 C.F.R. § 1.56(b). Thus, “a patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner.” *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991) (holding that Halliburton had no obligation to disclose cumulative references where “the cited references were more pertinent to the Halliburton application than were the withheld references”); *see also Jazz Photo Corp. v. ITC*, 264 F.3d 1094, 1110 (Fed. Cir. 2001) (affirming district court’s finding of no inequitable conduct because references considered by the examiner provided the same teachings as the undisclosed references). A reference shall be considered cumulative, and therefore non-material, when it “teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO.” *Regents of the Univ. of Cal. v. Eli Lilly and Co.*, 119 F.3d 1559, 1574-

75 (Fed. Cir. 1997). Accordingly, "if [a cited reference is] more closely related to the [application] than the uncited art, the applicant did not engage in inequitable conduct." *Id.*

D. No Rejections of Subsequent Claims Based on Previously Undisclosed References Is Probative Evidence That the Art Was Not Material to Patentability

The materiality of a reference may also be undercut by subsequent determinations by an examiner that similar claims were allowed despite subsequent disclosure of a reference. "The result of a PTO proceeding that assesses patentability in light of information not originally disclosed can be of strong probative value in determining whether the undisclosed information was material." *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1562 (Fed. Cir. 1984); *see also Life Techs., Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1327 (holding that patent examiner's conclusion that previously undisclosed information had "no bearing on the patents issued or the instant application" was "highly probative of its immateriality.")

IV. INTENT

An allegation of inequitable conduct cannot succeed absent clear and convincing evidence that the applicants deliberately and specifically intended to deceive the patent office. *Scripps Clinic & Research Found. v. Genetech, Inc.*, 927 F.2d 1565, 1574 (Fed. Cir. 1991); *see also Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998) (holding that "[i]n a case involving an omission of a material reference to the PTO, there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference."). Although intent may be proven by indirect evidence, a finding of deceptive intent cannot be based on mere inference or even on gross negligence; there must be "conduct, viewed in light of all the evidence, including evidence indicative of good faith, [that] must indicate sufficient culpability to require a finding of intent to deceive." *Hebert v. Lisle*, 99 F.3d 1109, 1116 (Fed. Cir. 1996). Thus, "Intent to deceive cannot be inferred solely from the fact that the

information was not disclosed; there must be a factual basis for a finding of deceptive intent.”

Id. Ultimately, to support such a finding, the party asserting inequitable conduct must prove “sufficient culpability to require a finding of intent to deceive,” *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), and a “deliberate decision to withhold a known material reference.” *Molins*, 48 F.3d at 1181.

Further, the standard for intent requires more than evidence of negligence or good-faith errors in judgment. *See Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1540 (Fed. Cir. 1984) (holding that, “Although the actions of [the applicant] and his patent counsel … should have been different,” the requisite intent was lacking because the failure to disclose information to the patent office amounted only to negligence or good-faith errors in judgment). “A patentee’s oversights are easily magnified out of proportion by one accused of infringement.” *Pfizer, Inc. v. International Rectifier Corp.*, 538 F.2d 180, 196 (8th Cir. 1976). Accordingly, intent to deceive must be determined “in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO.” *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990). “Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required.” *Id.*

Evidence that a previously uncited reference was subsequently disclosed to an examiner in a related application points away from an intent to deceive the PTO. The Federal Circuit has held that such subsequent conduct is “not consistent with an intent to deceive.” *Kimberly-Clark Corp. v. Proctor & Gamble Dist. Co.*, 973 F.2d 911, 918 (Fed. Cir. 1992) (finding the allegations that an applicant intended to deceive the patent office by failing to disclose information to be “without merit.”).

V. SCOPE OF INFECTIOUS INEQUITABLE CONDUCT

To prove infectious unenforceability, an accused infringer must first establish “inequitable conduct sufficient to hold at least one patent unenforceable before considering whether to hold an entire group of related patents unenforceable” *Speedplay, Inc. v. Bebop Inc.*, 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an “immediate and necessary relation” between the alleged inequitable conduct and enforcement of the related patents. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 675 (D. Del. 2004).

“[M]ere relatedness of subject matter is not a proper basis” to establish an immediate and necessary relation for purposes of infectious inequitable conduct. *Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 810-811 (Fed. Cir. 1990). To satisfy this requirement, the party alleging infectious inequitable conduct must prove that “the related patents either expressly incorporated the procedures of the invalidated patent or issued from continuation applications stemming from such, and where the patentee's inequitable conduct … in prosecution of the invalid patent forms a basis for its successful arguments in prosecuting the others.” *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 522, 526 (D. N.J. 2000) citing *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933).

Where claims are “substantially separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to the inequitable conduct committed in the parent application.” *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998).

“Inequitable conduct charges are disfavored by this court and charges of 'infectious inequitable conduct' even more so. Therefore, the court will narrowly construe the issue in

accordance with the Federal Circuit's jurisprudence." *Eaton Corp. v. Parker-Hannifin Corp.*, 2003 U.S. Dist. LEXIS 1014, *2 (D. Del., January 24, 2003).

VI. ADDITIONAL ISSUES NOT PROPERLY BEFORE THIS COURT

ACS believes that Medtronic has improperly raised the issues of inventorship and "examiner shopping." *See* Ex. 14. Accordingly, ACS maintains its objections to the introduction of any of these issues at trial. Nonetheless, ACS hereby states the respective issues of law.

1. INVENTORSHIP

Allegations of inequitable conduct for failure to join a co-inventor requires clear and convincing proof not only of the underlying claim of co-inventorship, but also of intent to deceive the patent office. *See Molins*, 48 F.3d at 1178; *Hess v. Advanced Cardiovascular Sys.*, 106 F.3d 976, 980 (Fed. Cir. 1997). Where an individual is shown not to be an inventor, the failure to disclose that individual as a co-inventor does not represent an intent to deceive the patent office. *See Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239, 261 (D.N.J. 1997).

2. "EXAMINER SHOPPING"

Patent Office practice dictates that "continuation applications normally are reviewed by the examiner of the parent application." Even in the event that a continuation application reaches a different examiner, the subsequent examiner is presumed to be aware of the other related applications, and as a result, any rejections therein. *See Leviton Mfg. Co., Inc. v. Universal Security Insts., Inc.*, 304 F. Supp. 2d 726 (D. Md. 2004) ("An examiner would have retrieved all related parent applications for review as required by the MPEP Chapter 904 which states that 'in all continuing applications, the parent applications should be reviewed by the examiner for

pertinent prior art.""). That a patent examiner did not review related file histories cannot serve to support a contention of inequitable conduct. Rather, "A patentee cannot be penalized for a patent examiner's dereliction of duty." *TM Patents v. IBM Corp.*, 121 F. Supp.2d 349, 372 (S.D.N.Y. 2000), citing *Nintendo of America, Inc. v. Magnavox Co.*, 707 F. Supp. 717 (S.D.N.Y. 1989).